DETAILED ACTION

Election/Restrictions

As noted in the attached interview summary, with a goal of negotiating allowable subject matter the examiner proposed cancelling the method claims (claims 127-140) and upon an updated search and review and approval from the supervisor sending out a notice of allowance for claims 125-126. The examiner noted that if claims 125-126 were found allowable and applicant was not willing to cancel the method claims that rejoinder would take place and an election of patient population for the method claims would be necessary to conduct an appropriate search. On 4/9/09 the examiner discussed the proposal with Carolyn Greene at which time applicants representative stated that they would discuss with the applicants. On 4/20/09 the examiner followed up with another phone call and discussed the proposal with Robert Murray at which time the applicants representative said that they were not willing to cancel claims at that point in time and requested the election in writing.

Claims 1-124 have been cancelled.

Claims 125-140 are new claims.

It is noted that the initial restriction requirement was sent out on 4/25/07. Instant claims 125-126 are within the scope of Group II of the original restriction requirement. It is noted that Group V of the original restriction requirement was drawn to a 'use' (see MPEP 2173.05(q)). The claims of Group V are interpreted as being drawn to a method of administering a compound. As such, instant claims 127-140 are within the scope of Group V of the original restriction

requirement. It is noted that the original restriction included an election of species of patient population (see page 5).

It is noted that the office action dated 7/30/08 set forth that claims 125-126 (drawn to compounds/compositions) and the inventions of claims 127-140 (drawn to methods of treating) are related as product and process of use. Since applicant previously elected Group II and a specific peptide on 8/27/07 such group and peptide was examined. As stated on pages 3-4 of the original restriction requirement (4/25/07) withdrawn process claims that require all the limitations of an allowable product claim will be considered for rejoinder. In the instant case, if claims 125-126 are found allowable (based on a final search and supervisors approval) claims 127-140 will be considered for rejoinder. However, in order to search claims 127-140 an election of patient population is required as set forth on page 5 of the original restriction requirement.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Condition treated: a specific species of patient population should be identified from those recited in claims 127-140. A specific embodiment should be identified. It is noted that claim 129 does not recite species (it recites subgenuses such as autoimmune disease) while claim 130 does recite species (such as rheumatoid arthritis), for example.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: Claims 127-129,133,135,137-140 are generic

There is an examination and search burden for the species due to their mutually exclusive characteristics. For example, claim 130 recites rheumatoid arthritis which is different from Stevens-Johnson syndrome of claim 131 which is different from organ transplant surgery of claim 136 for example. Each of the species are distinct patient populations and one of skill in the art would not recognize that every patient population would behave in the same way. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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